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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAQ, SHAFIQUL	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,774	KOSAKA ET AL.	
	Examiner	Art Unit	
	SHAFIQUL HAQ	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/21/06 and 8/29/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election-Restriction

1. Applicants' election of species in response to the restriction/election requirement of 2/5/09 is acknowledged. Applicants election of Chemical formula (3) set forth in claim 13 for a single species of "protein measurement indicator", the dye binding method set forth in claim 7 for "a single method for measurement of first response value" and the enzyme method set forth in claim 8 for a "single method for measurement of second response value" is acknowledged. Claim 14 does not read on the elected species.

   Because Applicants did not distinctly and specifically point out the supposed errors in the restriction/election requirement, the election has been treated as an election without traverse [MPEP 818.03(a)] and therefore, the requirement for restriction/election is still deemed sound and proper and is made final.

   Therefore claim 14 is withdrawn from further consideration as being directed to a non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of Claims

2. Therefore, Claims 1-13 and 15-17 are examined on merits.

Priority

3. This application is a 371 of PCT/JP2005/000758 filed 1/21/2005 and claims priority to JP 2004/016146 filed 1/23/04.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. With regard to claim 1, the recitation "when a liquid sample is mixed with a protein measurement indicator" is not a positive recitation and thus it is unclear whether mixing of the liquid sample with a protein measurement indicator is a required step in the method of measuring a protein. Further, claim 1 recites "based on the obtained information" in lines 5-6. It is unclear what information is intended to mean by "obtained information". Information of coloring occurring when the liquid sample is mixed with a protein measurement indication or the information of the creatinine concentration?

7. Claims 1 and its dependent claims 2-9, 11-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: 1) Step(s) of measuring protein concentration after mixing of liquid sample with a protein measurement indicator, 2) step (s) how the information reflecting a concentration of creatinine is the liquid sample is measured , 3) step(s) of how and what type of influence of the creatinine on a protein concentration is

eliminated and 4) a correlation step as to how the elimination of the influence of creatinine on a protein is correlated with the measuring a protein.

8. Claim 2 recites the phrase "based on coloring caused by a system containing the liquid sample and the protein measurement indicator" in lines 4-6. It is unclear what is intended to mean by based on coloring? Coloring of what? The phrase as recited does not require contacting the liquid sample with the protein measurement indicator in the system. "Caused by a system containing the liquid sample and the protein measurement indicator" does not indication mixing of the sample with the protein measurement indicator in the system and thus it is unclear what coloring is indicated by "coloring caused by a system".

   Lines 7-10 of claim 2 recites "a second step of obtaining a second response value which reflects a creatinine concentration in the liquid sample in a system containing the liquid sample but not containing the protein measurement indicator". It is unclear what system is intended for by a "system containing the liquid sample but not containing the protein measuremnet indicator"? The system does not require mixing the liquid sample with any reagent and thus it is unclear what method step(s) are involved in the system that measures creatinine concentration in the liquid sample?

9. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Lines 11-13 of claim 2 recites "a third step of calculating a protein concentration in the liquid sample, based on the first response value and inconsideration of the second response value". It is unclear what consideration of second response value is included or excluded by the term "inconsideration" in the claim.

10. With regard to claim 5, the claim recites "a corrected response value is obtained by correcting the first response value based on the first and the second response value" in lines 2-4. It is unclear, "based on the first and the second response value" what is being corrected to measure protein concentration in the liquid?

11. Claim 9 recites "a step of obtaining a plurality of responses for the respective liquid samples based on the first protein measuring procedure; a step of measuring a protein concentration in the liquid samples based on a second protein measurement procedure which is less susceptible to creatinine influence than the first protein measurement procedure; and a step of relating the responses to the protein concentrations measured by the second protein measurement procedure" in lines 5-12". As claimed there are two responses {i.e. 1. protein measured by first protein measuring procedure (i.e. response 1) and 2. protein measured by second protein measurement procedure (i.e. response 2)} and thus relating the protein measured by second protein measurement (i.e. response 2) to the protein measured by second protein measurement procedure (i.e. response 2) is unclear. Further, it is unclear what type of relation is intended to establish by the term "relating the responses" what step is involved in relating the protein measured by first protein measurement

procedure (i.e. response 1) to the protein measured by the second protein measurement procedure (i.e. response 2).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-3, 5, 8, 15, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Messenger *et al* (EP 0909953 A2).

With regard to claims 1-2 and 5, Messenger *et al* teach a method for measuring an analyte (e.g. albumin) based on a degree of coloring comprising reacting a first liquid sample with test strip containing reagents causing color change upon reaction with the analyte in the sample (a protein measurement indicator) to determine the uncorrected concentration (i.e. first response value) of the first analyte (e.g. albumin) and then information reflecting a concentration of creatinine (i.e. second response value) in second liquid sample is determined and based on the measured concentration of first liquid sample and the measured concentration of creatinine (i.e. based on the first response value and in consideration of the second response value), influence of creatinine on the protein concentration measurement is then corrected (see paragraph [0006] and claims 1-3).

With regard to claim 3, Messenger *et al* teach subtracting the influence of creatinine (i.e. elimination of the influence of creatinine) by determining a ratio of albumin and creatinine (paragraph [0007]).

With regard to claim 8, Messenger *et al* teach that common assays for measuring concentration of creatinine in second liquid sample include alkaline Jaffe and Benedict-Behre method (paragraph [0002]).

With regard to claim 15, for an indicator for measurement of a protein, use of redox dye or the like is suggested (paragraph [0001]) and a color reaction is measured because colorimetric analysis method is used and since means for measuring the uncorrected concentration of the first analysis object is a test strip, the indicator is considered to be held by a carrier in a dry state (paragraph [0006]).

With regard to claims 16 and 17, Messenger *et al* teach a first analysis object is albumin (paragraph [0006]) and a liquid sample is a body fluid, particularly urine (claims 2 and 9).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Messenger *et al* (EP 0909953 A2).

See the above teaching of Messenger *et al*. The reference teaches measuring uncorrected concentration of protein (e.g. albumin) and measuring concentration of creatinine and the influences thereof are eliminated to make a correction by the concentration of creatinine to measure the concentration of protein in a liquid sample accurately although the method of correction is different.

The method in the reference does not teach in which a calibration curve is determined and a formula is obtained as in the instant claims 4 and 6.

However, the method in which a calibration curve is obtained to make a correction is one of correction methods that are normally carried out by a person skilled in the art. What sort of correction method is to be employed is accordingly determined by a person skilled in the art according to the purpose and a required level of accuracy, and therefore is obvious to one of ordinary skill in the art absent unexpected results.

16. Claims 7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Messenger *et al* (EP 0909953 A2) in view of Waheed *et al* (Analytical Biochemistry 2000).

See the above teaching of Messenger *et al*. The reference teaches measuring uncorrected concentration of protein and measuring concentration of creatinine and the influences thereof are eliminated to make a correction by the concentration of

creatinine to measure the concentration of protein in a liquid sample accurately although the method of correction is different.

Messenger *et al* teach immunochromatographic and enzymatic method for measuring of protein (e.g. albumin) in first liquid sample but do not teach a dye binding method for measurement of protein.

Waheed *et al* disclose dye binding method for measurement of proteins (see title and abstract). Waheed *et al* teach that the dyes eosin B and eosin Y provides instantaneous color development with proteins and is applicable for estimating a wide rage of protein concentrations and the dyes can be used to estimate micro- and sub-microgram quantities of proteins (lines 1-3 of first column and lines 1-18 of second column on page 73).

Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to consider the dye binding method of Waheed et al in the method of Messenger *et al* for protein measurement in first protein sample, with the expectation of measuring a wide range of protein concentration with improved sensitivity with a reasonable expectation of success because Waheed *et al* teach that the dyes eosin B and eosin Y provides instantaneous color development with proteins and is applicable for estimating a wide rage of protein concentrations and the dyes can be used to estimate micro- and sub-microgram quantities of proteins.

With regard to claim 11, eosin B and eosin Y are xanthene dyes.

With regard to claim 12, eosin Y and eosin B dye of Waheed *et al* reads on the halogenated xanthene dye of Formula 3 and Formula 6.

17. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Messenger *et al* (EP 0909953 A2) in view of Waheed *et al* (Analytical Biochemistry 2000) as described above and further in view of Yip *et al* (US 5,385,847).

Messenger *et al* in view of Waheed *et al* teach dye binding method for measurement of proteins but do not teach immunoturbidimetric method or immunolatex agglutination method for measuring proteins that is less susceptible to creatinine influence.

Yip *et al* describe a method for measurement of creatine and other water-soluble proteins and as a method for measurement of protein, an immunoassay, particularly a coagulation method is employer (see claim 1). Yip et al disclose that immunological methods such as immunoturbidimetry method can measure urinary albumin at a low concentration.

Therefore, it would be obvious to one of ordinary skill in the art to include immunoassay method for measuring albumin because immunological methods can measure urinary albumin at a low concentration (Yip *et al*) and it is easily conceivable by one of ordinary skill in the art that since immunological method involves specific recognition of albumin, the method would be less susceptible to creatinine influence and thus the method would be more accurate to provide albumin concentration in urine.

With regard to claim 10, Yip *et al* teach immunoturbidimetry method and immuno agglutination method for measurement of proteins (Lines 54-58 on column 1 and lines 13-16 on column 3).

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/
Examiner, Art Unit 1641